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Acknowledgement

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The International Center for Research on Women provided an opportunity to explore micronutrient delivery from a more social science perspective. Charlotte Johnson-Welch and Kathleen Kruz were most capable collaborators, and working with them has been both enjoyable and productive.

OMNI Research offered an opportunity to work closely with many talented scientists who are dedicated to improving the lives of children and the families around the world. Their efforts on behalf of OMNI Research yielded the project's successes.

Dr. Penelope Nestel, OMNI Research consultant and previously Nutrition/Research Advisor for OMNI, deserves special recognition for her efforts in guiding a number of the OMNI Research projects and helping the HNI staff gain a greater understanding of the challenges facing micronutrient programs. She is a gifted scientist and graciously shared her expertise with this project.

The OMNI Research Peer Review Panel (PRP) members were critical to the success of this project. They offered their time to develop the request for proposals and shared their research and expertise with the principle investigators. In particular, those PRP members from food and food ingredient companies provided insights not often available to developing scientists.

Finally, the HNI staff deserves recognition for successfully completing the largest research undertaking ever attempted by ILSI. Dr. Paula Trumbo provided the scientific leadership, contributing significantly to the development of many of the research projects and to the workshops and publications. Mr. Dwayne Milbrand is to be commended for his careful monitoring of the financial resources of OMNI Research. Other ILSI staff, including Paula Murphy, Associate Legal Counsel, the Accounting Department staff and other HNI staff (Kathy Krolak, Dotty Foote, Melinda Thomas) are to be commended for their important contributions to the success of the cooperative agreement.

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Executive Summary

The United States Agency for International Development (USAID) and the International Life Science Institute (ILSI) Research Foundation with its partner, the International Center for Research on Women (ICRW), have completed a 6.5-year cooperative agreement that supported research and information dissemination efforts aimed at improving delivery of vitamin A and iron to those at risk of deficiency in developing countries. This agreement expended \$7,788,794 to support 39 research grants, 6 expert panel consultations, 15 primary publications, and 44 other publications and presentations.

The research grants provided a vital opportunity to fund innovative ideas offered by university-based scientists in developed and developing countries as well as nongovernmental organizations (NGO) experienced in implementing micronutrient programs. The ICRW portion of the agreement had research capacity building as a primary objective. The grants addressed a wide range of topics from assessment methodology to the impact of community health workers on micronutrient consumption. New insights were gained regarding ways to improve delivery of supplements, innovative fortification opportunities (“sprinkles”) and ways to enhance quality assurance in food fortification programs, and the role of infection in vitamin A status.

The expert panel consultations and publications were important vehicles to achieve consensus within the scientific community on a specific topic, to identify research gaps, and to disseminate this information to the broader community. OMNI Research also contributed to the initial stage of the VITA public-private partnership effort by helping USAID make contact with potential private sector partners.

In addition to providing new information, scientific research usually generates questions for future research. This was true for OMNI Research. Process experience was generated also and can be used to develop smarter operational research projects funded by USAID in the future. There are few sources of funding for this type of research because of its largely applied or operational nature. Without USAID support for this vital type of research, it will be much more difficult to reach the goal of preventing micronutrient malnutrition.

Objectives of the Cooperative Agreement

OMNI Research was designed as a five-year program to support technology development through 1) research to develop new or improved micronutrient assessment techniques and 2) research to identify new and innovative technologies for delivery of micronutrients to vulnerable groups. Vitamin A and iron deficiencies were the focus of the research and other activities.

OMNI Research was also designed as a parallel project to OMNI (Opportunities for Micronutrient Interventions), a contract with John Snow, Inc. to provide short and long term technical assistance to vitamin A and iron programs in developing countries. OMNI Research was to be the testing ground where problems or bottlenecks identified by OMNI

in field programs could be solved. Both projects began at the same time. OMNI Research extended beyond the close of OMNI because of no-cost extensions made by the USAID.

The central challenge for OMNI Research was to develop new knowledge that would be useful for improving the delivery of micronutrients (specifically vitamin A and iron) in developing countries. The goal was to provide grants to entrepreneurial people in these countries who had innovative ideas that could be linked to improving micronutrient programs.

ILSI Research Foundation asked ICRW to contribute to preparing a proposal to the OMNI Research Request for Application (RFA). This invitation was based on the recognition that improvements in individual's micronutrient status was severely limited by gender-related issues including women's access to resources and their decision-making autonomy. Moreover, it was the explicit intention that ICRW's portion of OMNI Research activities would also aim to strengthen capacity of developing country researchers and program practitioners in designing, conducting and evaluating research that would directly impact program practice. To do so, ICRW received funds to conduct three workshops (proposal development, advocacy strategy, and reporting and synthesis of research findings) and make site visits to provide direct technical support to research projects underway. Thus, building capacity for scientific research was a primary component of the ICRW work. A full report of the work carried out by ICRW is included as Appendix 1. Because ICRW-supported studies were an integral part of OMNI Research, information on the process used by ICRW and the findings of these studies is integrated into appropriate sections of this report.

The OMNI Research Process

During the course of the cooperative agreement, OMNI Research funded research, organized and held workshops, and developed publications. The process used to identify activities and carry them out is described below. In total, 39 research projects were funded (Table 1).

Peer Review Panel: As required by the cooperative agreement, a twenty-member Peer Review Panel (PRP) was appointed at the outset to help guide OMNI Research. The members of the PRP represented a variety of expertise related to specific micronutrients (vitamin A, iron, and iodine) and specific strategies for preventing micronutrient malnutrition (supplementation, fortification, and nutrition communications/behavior change). A list of the PRP members is in Appendix 2. Through its food industry membership, ILSI was able to secure participation of four scientists from the food industry in the PRP at no cost to the project. An ICRW staff nutritionist also served on the PRP. This ICRW representation created an opportunity for the PRP to directly impact both the ICRW and the ILSI Research Foundation-supported research activities.

The Peer Review Panel met four times during the course of the project. At the initial meeting, held February 3-4, 1994, at the ILSI office in Washington, the panel heard from

representatives of organizations involved in preventing micronutrient malnutrition, i.e., USAID, UNICEF, World Bank, and the Micronutrient Initiative, regarding research priorities.

At the initial meeting, the PRP identified five areas for research emphasis. Three additional areas were identified at the second meeting of the PRP (November 30 – December 1, 1994). These eight topics were:

- ? quality assurance and control system for vitamin A, iron, or iodine fortified food,
- ? development and validation of simple methods for individual assessment or rapid community screening of iron, vitamin A, and iodine deficiencies,
- ? development of strategies to increase and test bioavailability of vitamin A and iron from diets,
- ? effective communications to resolve micronutrient deficiencies,
- ? assessing costs of micronutrient interventions,
- ? development of improved delivery systems for iron supplements,
- ? development of improved field methods for testing micronutrients in fortified foods,
- ? development of improved methods for processing and packaging fortified complimentary/weaning foods.

The ICRW studies comprised a ninth topic of study, that is, reduction of gender constraints in order to minimize micronutrient deficiencies at a household level. Unlike the above topics that were identified in concert with the PRP, this particular focal area was articulated as a key area of need in the joint proposal submitted by ILSI Research Foundation and ICRW in response to the OMNI Research RFA. This study topic supports not only the strategic objectives of the USAID Center for Population, Health and Nutrition, it also supports USAID's commitment to gender and development, as articulated in its Gender Plan of Action.

Subgroups of the PRP were identified to draft the Request for Proposals (RFP) for each of these nine categories. These same subgroups reviewed the proposals received for scientific merit and recommended those to be funded. One member of the PRP was assigned to monitor the scientific progress of each proposal that was funded. ICRW used a similar process, although the PRP members working with ICRW also provided on-site technical support to the grantees and were paired with ICRW staff members as technical monitors for each of the five studies supported by ICRW.

Large portions of the third meeting (December 11-12, 1995) and the fourth meeting (May 28, 1997) of the PRP were devoted to how to capture the relevant findings from the research funded and disseminate this information to program managers and planners in developing countries. A series of reporting-out workshops were recommended. During the third meeting a list of key research gaps was developed to guide identification of additional projects to support.

OMNI Research covered the travel and per diem costs for the non-industry PRP members to attend the PRP meetings. An honorarium was offered to non-industry members to cover the time they spent in developing an RFP, reviewing proposals, and monitoring an on-going project. With the exception of the grants funded by ICRW, no funds were available for site visits of funded projects by PRP monitors.

Requests for Proposals: The nine RFPs issued by OMNI Research (Appendix 3) were released one at a time over the course of 1994 and 1995. Each listed specific research questions for which proposals were being sought, provided an idea of the level of funding that should be requested, estimated the number of projects that would be funded, and asked for a succinct scientific proposal (limited to 5 pages of text) with budget. Indirect costs were limited to ten percent of the total budget. Criteria of successful proposals were included to help guide the investigator in developing his/her project. No limitations were placed on where the work in the project was to be done. However, the OMNI Research staff informally encouraged investigators based in the United States or other developed countries to pair-up with developing country scientists in preparing proposals. ICRW also required all applicants to represent partnerships between NGO or implementing agencies and research institutions, required the proposed research be linked to an on-going (or newly completed) program, and required the research to use both social and bio-medical scientific methods and procedures.

The RFP were circulated to a mailing list assembled by ILSI, which relied heavily on the International Vitamin A Consultative Group (IVACG) or the International Nutritional Anemia Consultative Group (INACG) mailing lists. Information about these RFP was available on the ILSI web site. ICRW's RFP mailing list included developing country research institutions, NGO, and other non-research institutions in addition to the ILSI Research Foundation list. The number of proposals received varied from 91 for the ICRW RFP to 12 for the RFP on improved methods for testing fortified foods.

Deadline for receiving proposals was set approximately six months after the release of the RFP. All proposals received were given to the appropriate PRP subcommittee to review. Reviewer guidelines were provided based on similar tools developed for other ILSI grant programs. Each proposal was scored for the following components:

- ? global impact on specific micronutrient malnutrition (10 points),
- ? knowledge of proposed work and past experience of the principal investigator and collaborators (10 points),
- ? methodological approach (50 points),
- ? research environment/likelihood of success (25 points),
- ? justification of budget (5 points).

Those proposals receiving the top number of points were judged to be of scientific merit for funding. A second review was conducted with input from USAID and OMNI staff to determine if the proposal was of interest programmatically. The goal was to identify proposals that were scientifically sound, but at the same time innovative in their approach to operational problems. In some cases, proposals identified by the PRP were innovative,

but technically weak. OMNI and OMNI Research staff worked with these investigators to strengthen these proposals.

A third level of review was carried out by the appropriate USAID mission. Some missions declined to have proposed projects carried out in their country. Several missions asked that the RFP not be circulated to scientists in their country. Discussions with the missions slowed the process of releasing the RFP and making awards.

ILSI also reviewed each proposal being considered for funding for ethical issues. The ILSI policy on research using human subjects is strict. Procedures that would not be funded in the United States were not allowed, no matter where the research was to be carried out. Institutional Review Board approval or the equivalent was required. This process included the use of informed consent. Several proposals were not funded or were modified before funding because of human use issues.

ICRW used a similar review and weighting process. However, ICRW also invited seven finalists to a proposal development workshop as part of the selection process. Five of these were eventually funded.

Once a proposal successfully passed all three levels of review, a grant agreement was signed by both parties using the grant proposal as the description of work to be performed. A payment schedule was included that was tied to the delivery of progress reports. The final payment was linked to the delivery of an **acceptable** final report. A PRP member with appropriate expertise was assigned as the project monitor and encouraged to interact with the investigator by fax, phone, or email. The role of the project monitor was to follow the development of the project and offer suggestions on study design, methodology, data management, and statistical analysis. All progress reports and the final report were reviewed by the monitor and comments/suggestions relayed to the investigator. While some monitors were very involved with their projects and provided significant help, others were less active.

For two of the RFPs, none of the proposals submitted successfully matriculated through the review process. These topics were 1) assessing costs of micronutrient interventions and 2) development of improved methods for processing and packaging fortified complimentary/weaning foods.

Non-RFP Process: After the nine RFPs were issued, OMNI Research began to fund projects that were not solicited through a competitive process. This decision was made for a variety of reasons, including: the reluctance by some USAID missions to allow projects to be funded in their country; more direction as to needed research coming from OMNI; and a growing number of high quality, unsolicited proposals that came to OMNI Research. Many of the RFP projects were not hypothesis-driven. Of the total of 39 projects funded over the life of OMNI Research, 16 were funded through the non-RFP route.

The review process was exactly the same. A PRP subgroup was identified for each proposal, review was conducted on the scientific and programmatic level, and mission concurrence was sought, where necessary. For several of the non-RFP proposals, the scientific review was done by experts who were not part of the PRP. The same human use standards were applied as well.

OMNI Research Expert Panel Consultations: During the course of the cooperative agreement, six consultations were planned and executed (Table 2). Two of these (the quality assurance and the dietary assessment methodology workshops) were designed as reporting-out workshops for the purpose of placing the findings of OMNI Research projects into the broader scientific context and drawing out specific programmatic recommendations. These topics were identified by the PRP at their third meeting. Other topics were also identified, but workshops on these topics were never organized.

For the reporting-out workshops, experts in the field (along with the OMNI Research investigators who had completed appropriate projects) were invited to Washington to discuss the general area of interest. An effort was made to include a sizable number of developing country representatives with programmatic expertise. The output of both consultations was to be a document giving new guidance on the particular topic.

Three of the consultations were identified by USAID and OMNI staff as important activities for OMNI Research. Publications were generated by each of these three.

The OMNI Research Evaluation Workshop was held at the end of the cooperative agreement and provided an opportunity to critically review both the findings of the funded projects and the process for selecting and monitoring these projects. The information provided under the “lessons learned” segment of this report was developed through the evaluation workshop. The final report from each completed project was reviewed in advance of the workshop by two external experts. They were given a list of questions to answer in preparing their written review. All of the reviews were compiled into a booklet and circulated to all of the participants at the workshop. Three individuals from developing countries with programmatic expertise were asked to participate in the workshop. At the workshop each project was discussed with the larger body and a list of follow-on project was developed. The latter appear in the recommendations section of this report.

OMNI Research Publications: OMNI Research has published a number of individual documents as the output of specific research projects and workshops (Table 3). In some cases (four of the publications) an expert panel review process was used that involved identifying a consultant(s) to develop a draft document(s), and then having a larger group review the document(s) through a workshop. In other cases, the author was invited to develop the document based on his/her expertise.

One document was designed for publication in a peer-reviewed scientific journal. All others were designed for more practical, field audiences. The expected output from the dietary assessment reporting-out workshop was not written.

OMNI Research publications have been and continue to be circulated in response to requests from individuals. Notice of the availability of documents is posted on the ILSI website. Availability of new publications is announced using postcard mailers, and publications are distributed at IVACG/INACG meetings. For example, the first edition of the vitamin A inventory (600 copies) was distributed at the XIX IVACG meeting in March 1999 in Durban, South Africa. The publications are free to individuals in developing countries, but US\$3.50 is charged for publications going to developed country individuals. These funds are then returned to USAID.

Over the course of OMNI Research, 2474 copies of these publications were distributed (6720 copies printed). These publications will continue to be available from ILSI through the Micronutrient Global Leadership Cooperative Agreement.

ICRW prepared and disseminated a set of seven reports to over 800 development practitioners, researchers, and policy makers. These reports included five country-specific research summary reports, a synthesis of research findings from the set of studies, and a conceptual framework that defined the women-centered approach used by the studies. The documents were also posted on the ICRW website and submitted to USAID's Development Experience Clearinghouse. See ICRW's final report, Appendix 1, for a complete listing of articles, conference presentations, and other dissemination activities.

OMNI Research encouraged its grantees to publish their findings in peer-reviewed scientific literature or other appropriate vehicles.

Other OMNI Research Activities: Appendix 4 lists consultants hired by OMNI Research to carry out specific functions such as developing draft documents for publication and working with ongoing research projects. One of the more in-depth activities was the grant to the National Academies of Sciences' Board on International Health to summarize what strategies are available to prevent micronutrient malnutrition. This project involved setting up an expert panel to review the current state of knowledge and offer their best advice based on data that was available.

VITA – Vitamin A Enhanced Effort

OMNI Research aided USAID in organizing a public-private partnership to promote vitamin A activities. Through ILSI's food industry network, OMNI Research was able to encourage collaborative efforts between USAID and a number of food and food ingredient companies (Appendix 5). ILSI helped organize face-to-face meetings between USAID and representatives of these companies to discuss their interest in working with the VITA partnership.

Mr. Roger Moffat served as a short-term consultant to help organize a high-level USAID meeting with the private sector partners in March 1999. A declaration was signed by those present committing their companies to working with USAID to deliver vitamin A

to needy people in developing countries. OMNI Research also supported the production of video material on vitamin A to use at the high-level meeting.

Following the March 1999 VITA meeting, the ongoing VITA activities were carried out by the MOST project. OMNI Research staff continued to provide a limited level of support when requested.

Lessons Learned – Significance and Impact of the OMNI Research Activities

These will be presented in terms of the research sponsored by OMNI Research, other activities, and the process used.

Lessons learned from sponsored research (by categories used at the evaluation workshop): The majority of these lessons were identified by the experts invited to participate in the OMNI Research Evaluation Workshop. A list of projects with individual findings and limitations is provided as Appendix 6.

? Dietary assessment and improvement, including factors that affect absorption

Findings with potential programmatic relevance include:

1. Processing dark green leafy vegetables (pounding and homogenizing) appears to improve the availability of provitamin A (Takyi). Further investigation is needed on actual impact on biological pathways.
2. Dietary analyses at population level are useful for assessing population risk of iron and zinc deficiencies (Gibson). The methods employed by Gibson should be extended to other nutrients. Other population subsegments need to be examined for applicability. These methods do not appear to be useful at the individual level.

In addition, the need to bring behavioral scientists and laboratory scientists together to design appropriate studies was made evident again. Proper experimental design is essential to move from laboratory evidence to demonstrating effectiveness in the field. Adequate time for impact to occur is also necessary. The ICRW studies went a step further in requiring collaboration between researchers and program practitioners. This created the opportunity to ensure that research is used to meet the needs of programs.

? Iron laboratory indicators and bioavailability

Findings with potential programmatic relevance include:

1. The ferrous fumarate “sprinkles” offer promise as a low-cost vehicle for delivering micronutrients to infants consuming complementary foods in a variety of locations (Zlotkin). Quality control in the encapsulation process is essential.

2. Disodium EDTA offers potential to enhance absorption of iron and other minerals when added to foods with low bioavailability of these nutrients (Nelson). Control of potentially confounding environmental factors, i.e., use of non-fortified food by the sample population, is necessary.

These studies reaffirmed that distinguishing between anemia and iron deficiency anemia is absolutely necessary in order to be able to interpret results. The distinction must be carried throughout the study design (subject selection, biochemical indicators, and analysis of response to intervention). Furthermore, it is essential that the amount of the micronutrient fed be great enough to actually have an measurable impact.

? Vitamin A indicators including infection markers and their impact on vitamin A measures

Findings with potential programmatic relevance include:

1. The RBP:TTR ratio may prove useful once additional data controlled for infection are available and a cut-off determined (Rosales).
2. Chronic, subclinical inflammatory state is associated with less reduction in plasma retinol than current, subclinical infection (Thurnham).
3. Though the breastmilk analysis for vitamin A was not impressive, breastmilk (causal sample) analysis for iodine is a promising non-invasive method for determining prevalence of iodine deficiency (Stoltzfus).

? Behavior change including supplement distribution

Findings with potential programmatic relevance include:

1. “Tailored counseling,” meaning negotiation between a counselor and the audience to determine where people are (readiness for a desired behavior), is an important process (Fishman-Parvanta).
2. Attractive packaging of supplements may be a critical component of encouraging supplement consumption (Seshadri).

Successful projects were those that targeted a specific and measureable behavior. Multidisciplinary teams are perhaps more likely to generate successful research efforts. Care must be taken to validate secondary data, i.e., wages and worker productivity to rule out potential confounding.

? Quality assurance for food fortification

Findings with potential programmatic relevance include:

1. Effective instructional materials used in promoting quality assurance for food fortification (de Arriola and Fornasini) improved the quality of the final food product. A manual showing what works is now feasible.
2. Initial effort on developing a test kit for determining iron content in fortified foods (Miller) is promising and should be explored further by the private sector.

? Women in development

Findings from the ICRW-managed research projects include:

1. Investing in women's access to resources yields nutritional results.
2. Investing in women's capabilities as decision-makers and managers yields nutritional results.
3. Investing in both access and decision-making yields effective and efficient food-based interventions.

Lessons Learned from Expert Panel Consultations and Publications: The OMNI Research Evaluation workshop did not review the output from the expert panel consultations (Table 2). All were successful in bringing together knowledgeable individuals from developing and developed countries to discuss a specific subject. With one exception (the dietary assessment workshop), all resulted in a document that summarized the state-of-knowledge and, when appropriate, offered specific programmatic guidance. These documents became OMNI Research publications.

In addition to these consultations, OMNI Research funded a project through the National Academies of Sciences Board on International Health to develop a report on proven strategies for preventing micronutrient malnutrition. The Board on International Health put together the group of experts and organized a consultation to discuss several background papers authored for the group. The output, which was published by the National Academy Press, is "a conceptual framework based on past experience that will allow funding organizations to tailor programs to existing regional/country capabilities and to incorporate within these programs the capacity to address multiple strategies ('toolchest') and multiple micronutrient deficiencies" (NAS 1998). This framework marks a major shift in how prevention of micronutrient malnutrition is viewed. The report also called attention to "the almost total lack of attention in program design and implementation to the systemic collection of data on costs linked to program components and effectiveness of different interventions" (NAS 1998). This report serves as the scientific support for USAID's current interest in supporting fortification in combination with targeted supplementation as a more sustainable prevention strategy than supplementation alone.

Other OMNI Research publications were developed from the funded research, i.e., *An Interactive 24-hour Recall for Assessing the Adequacy of Iron and Zinc Intakes in*

Developing Countries, by Gibson and Ferguson. A series of publications was developed from the ICRW projects highlighting the synergy between women in development and micronutrient projects. The Draper project (a multi-center study on perceptions about iron supplements for infants and young children) will also become a publication in the very near future.

Several other documents were developed with the goal of guiding USAID and other donor organizations in pinpointing data gaps. These included *The Effect of Vitamin A Nutriture on Health* (Nalubola and Nestel) and *Inventory of Current Vitamin A Research and Program Activities Related to Child Survival in Developing Countries* (Nalubola and Nestel). The latter document is meant to be updated on a regular basis and contains information about ongoing research projects and programs from around the world. It has proven useful in guiding decisions on where research funds should be spent.

Lessons Learned Regarding the Research Grant Process Used: The OMNI Research Evaluation Workshop participants identified a number of lessons learned that should be applied in subsequent grant programs. These include:

- ? Using a pre-proposal or concept paper as the initial step to allow USAID more flexibility in formulating the research to be conducted. A research review team could be identified with USAID and external experts to review the pre-proposal. If the proposal was accepted, then a more detailed proposal with in-depth information (more than 5-pages) would be requested.
- ? Closer monitoring of project progress is necessary to insure the highest quality of output. Use of control points or stop-gaps in the research cycle may be useful in making sure that early phases of a research project are completed successfully before moving on to the next phase. Even some of the most experienced researchers turned in reports that were not acceptable. Project monitors need more guidance on what they are expected to do. Experience with developing country research is an important criteria for selecting monitors.
- ? Capacity building should not be considered as an end in itself. Rather it is a means to achieving excellence in research. Resources for site visits should be provided.
- ? More emphasis should be placed on reporting requirements early in each project so that the investigator is able to provide a final report that meets the needs of USAID. This includes more attention to design issues to ensure that the data collected are appropriate to test the hypothesis.
- ? External review of final reports is useful in improving the quality of these reports.
- ? A larger cooperative agreement staff should have been in place to give each project the attention it deserved.

- ? If an RFP process is used, USAID missions should be involved in the process from the beginning.

Recommendations for Future Activities

A number of the research projects generated ideas that need further research. These include:

- ? Sprinkles are an innovative, attractive concept because they are a food-based approach that can be managed by the mother. Their use empowers women and may potentially lead to other health-seeking behaviors. Sprinkles with iron and other micronutrients need to be studied further to determine effectiveness and real-world cost implications.
- ? Additional basic research is needed to understand the mechanism by which elevation of acute phase proteins in response to infection, chronic or current, alters plasma retinol.
- ? Intermediate behavior trials for nutrition are important because the endpoints measured are available in a much shorter time period than is required to see a change in biochemical indicators in response to the behavior change. Pilot trials can provide useful information before large-scale behavior trials are undertaken.
- ? Adapt the quality assurance instructional materials developed in Central America to the needs of other countries and begin to focus attention on the need for quality.

The OMNI Research Evaluation Workshop generated a list of additional products that should be developed to ensure that the lessons learned from the OMNI Research activities are passed on for others to learn. These include:

- ? publication of the quality assurance manual,
- ? a decision tree for selection of dietary methods appropriate for risk/benefit analysis,
- ? a user friendly version of the Gibson manual on dietary assessment for iron and zinc,
- ? a short statement on the use of dietary methods to assess the study population's risk of deficiency,
- ? a policy brief on the distinction between anemia and iron deficiency anemia so that attributable risk can be quantified in a population. Make this available through well-read documents such as SCN News.
- ? a research note on how to do vitamin A and iron "exposure estimations in relation to the expected effect,
- ? a research note on vitamin A assessment methods under development,
- ? a decision tree to help determine the appropriate tools for behavior change operational research,
- ? an inventory of available behavior change tools and materials,

- ? a case study of the participatory approach for behavior change, including use of traditional media,
- ? a policy brief on how to establish a culture that requires quality assurance,
- ? incorporation of the food composition knowledge gained into appropriate food composition data bases.

In terms of the process used in OMNI Research, it is necessary to provide more scientific oversight in future projects that offer research grants. While the goal is not necessarily a peer-reviewed publication, the overall quality of the data generated would be enhanced if more staff and travel resources were available for monitoring projects. A mechanism should be in place throughout any follow-on projects to provide strategic focus for the research questions to be addressed. Research is a long-term activity. USAID has a very distinguished record in funding high quality micronutrient research. This commitment should be sustained in the future.

VITA offers USAID a beneficial partnership with private industry and non-governmental organizations. Additional resources, especially staff time dedicated to building a strong partnership will result in increased availability of vitamin A fortified foods in developing countries.

In addition, OMNI Research offered an opportunity to explore broad programmatic issues through its reporting-out workshops and expert panel consultation. These activities are valuable for summarizing the state of knowledge and identifying ways to move forward on specific operational issues. Such activities should be a part of any follow-on activities.

Significance of the Cooperative Agreement's Activities to AID and Research and Development

OMNI Research has contributed new knowledge that is relevant to two of the strategic objectives of the USAID Center for Population, Health and Nutrition. These are SSO 2 – Increased use of key maternal health and nutrition interventions, and SSO 3 – Increased use of key child health and nutrition interventions.

The goal of OMNI Research was to improve interventions. Food fortification is a primary intervention to prevent micronutrient malnutrition in both women and children. OMNI Research contributed significantly to improving food fortification through its work on sprinkles and the contribution that quality assurance systems can make to improving the availability of vitamin A and iron.

OMNI Research provided tools (tailored counseling and empowerment of women) that could be pursued to enhance behavior change relative to food selection habits. These are important to implementation of a broader array of interventions as recommended by the National Academies of Sciences report sponsored by OMNI Research.

Improved methodologies were also a result of OMNI Research investments, particularly an advancement in understanding the confounding role of infection in vitamin A deficiency through the Wellcome Trust/USAID expert consultation and subsequent meta-analysis.

Successful strategies to prevent micronutrient malnutrition can be generated out of efforts aimed at improving women's access to sound nutrition information, access to technology, and decision-making skills and opportunities.

Public-private partnerships offer great potential for leveraging scarce resources to combat micronutrient malnutrition. Such partnerships require time and effort to develop. Care must be taken to ensure both time and effort are allotted to any partnership activities.

Finally, the OMNI Research experience offers documentation of the difficulty of carrying out this sort of research. Attention to process issues can help to ensure better research results for USAID in the future

Papers Written or Presentations Given on the Cooperative Agreement or Its Individual Components

In addition to the expert panel consultations listed in Table 2 and the publications listed in Table 3, other publications and presentations based on OMNI Research activities are listed in Appendix 7. As many of the studies funded by OMNI Research have finished in the past few months, it is reasonable to expect this list to continue to grow for sometime to come.

Fiscal Report

The final financial status report (SF 269A) was submitted to the appropriate individuals within USAID. The cooperative agreement spent a total of \$7,788,794 during its 6.5-year life, out of the \$7,815,569 obligated.

Figure 1 shows a breakdown of how these funds were expended. The research category includes all funds spent on research grants (48 percent of the total expenditures). Other activities included all expert panel consultations, publications and consultant costs (36 percent of the total expenditures). Administration included all direct costs associated with the cooperative agreement (16 percent of the total expenditures). The funds spent on indirect costs over the life of the agreement were \$707,395. The amount varied annually and was consistently below the provisional approval level of 20 percent.

Table 1: Research Projects Funded By OMNI Research

Investigator	Title	Time Frame	Country	Type of Study
Dr. Namanjeet Ahluwalia	Evaluation of Iron Status of Children in Presence of Infection: Effects of Iron Supplementation on Iron Status, Infection and Morbidity	1998-2000*	USA/ Sri Lanka	I
Dr. Lindsay Allen	Practical Food Sources of Ascorbic Acid to Increase Dietary Iron Bioavailability	1995-1997	USA/ Mexico	M
Dr. Paul Arthur	A Randomized Double-blind Placebo Controlled Trial to Evaluate the Impact of Vitamin A Supplementation on Maternal Mortality in Ghana	2000*	Ghana	I
Dr. John Beard	Prevention of the Negative Behavioral Effects of Iron Deficiency in Mothers	1998-2000*	USA/ South Africa	I
Dr. Louise Canfield	High Carotene Fruits and Vegetables as a Potential Source of Vitamin A in Breast Milk of Honduran Women	1996-1999	USA/ Honduras	I
Ms. Maria de Arriola	Evaluation and Documentation of a Quality Assurance and Control (QAC) System of Fortified Foods in Honduras	1995-1997	Guatemala	BP
Dr. Helene Delisle	Validation of a Simplified Dietary Method for Assessment of a Vitamin A Deficiency Risk in Niger	1995-1997	Canada/ Niger	M
Dr. Alizon Draper Dr. Lalini Rajakapsa Dr. Hilary Creed-Kanashiro Dr. Sam Akor Dr. Ram Shrestha	Drug Dispensing Issues for Infants and Yoing/Children: Formative Research into Factors Influencing the Acceptability of Iron and Multi-micronutrient Supplements and Different Dispensing technologies	1998-2000	Sri Lanka	BP

Ms. Matha Burdick de Piedrasanata	Adaptation and Use of Quality Assurance Methods for Evaluating a Vitamin A Communications Strategy in Guatemala	1996-1997	Guatemala	I
Dr. Claudia Fishman	Trial of a Community-Based Intervention Using New Behavior Change Theories to Improve the Micronutrient Status of Women and Children in Bangladesh	1997-1999	USA/ Bangladesh	I
Dr. Marco Fornasini	Analysis of the Strategies Used for Quality Assurance and Control System (QAC) by the Program Operational Fight against Endemic Goiter and Cretinism in Ecuador	1995-1997	Ecuador	BP
Dr. George Fuchs	Dietary Fat and Infection: Relationship to Vitamin A Status of Women and their Infants Breastmilk Retinol/Carotenoids, and Dietary Assessment Methodology	1995-2000	Bangladesh	I
Dr. Zwedie Wolde Gebriel (ICRW)	Improving Micronutrient Outcomes through a Problem - Solving Approach to a Women's Diary Goat Production Project	1996-1999	Ethiopia	I
Dr. Rosalind Gibson	Use of Biomarkers to Validate a Dietary Tool Designed to Assess Risk of Inadequate Intakes of Iron and Zinc in Developing Countries	1995-1997	Canada/ Malawi	M
Dr. Tara Gopaldas	A Multi - Nutrient Package for Tea Plantation Workers for Better Health Productivity and Profitability	1996-1998	India	I
Dr. Suraiya Ismail	Health and Nutrition in Central Asia	1996-1997	UK/ Kazakhstan	Survey
Dr. Jackson Kabira (ICRW)	Testing the Effects of Women Farmers Adoption and Production of Orange Sweet Potato on Vitamin A Food Intake	1996-1999	Kenya	I
Dr. Mohammed Khan/Mr. Kapil Kaul	Development of Improved Systems for Iron Supplements	1996-1999	India	BP
Mr. Balbir Mathur	A Test of Social Marketing to Increase the Dietary Use of Vitamin A-Rich Drumstick Leaves by Rural People in India	1996-1997	USA/ India	I

Dr. Dennis Miller	A Field Method for Testing Iron in Fortified Foods in Peru	1996-1999	USA/ Peru	M
Dr. Walter Miranda	Iron Supplementation through Community Health Workers	1996-1999	Nicaragua	BP
Mrs. Generose Mulokozi (ICRW)	Women and Solar Drying Technology: Impacts on Income and Micronutrient Status	1995-1997	Tanzania	I
Dr. David Nelson	EDTA to Reduce Anemia	1995-1997	Ecuador	I
Ms. Somluck Nimsakul	Validity of Vitamin A Dietary Intake Methodology: Effect of Dietary Fat and Infection	1995-2000	Thailand	M
Dr. Francisco Rosales	Effects of Inflammation on the Response of MRDR and the RBP: TTR Ratio to Vitamin A (VA) Supplementation during Early Infancy	1999-2000	USA	M
Dr. Francisco Rosales	Validation of the Ratio of Serum Retinol-Binding Protein (RBP) to Transthyretin (TTR) as an Indicator of Vitamin A	1998-1999	USA	M
Dr. Catherine Ross & Dr. Francisco Rosales	Validation of the Ratio of Serum Retinol-Binding Protein to Transthyretin as an Indicator of Vitamin A Status	1997-1998	USA/ Papua New Guinea	M
Dr. Nair Carrasco Sanez (ICRW)	Reducing Iron Deficiency Among Users of Peri-Urban Community Kitchens	1996-1998	Peru	I
Dir. Gen. Senaratne	Efficiency Trial for Iron Fortified Wheat Flour	1998-2000*	Sri Lanka	I
Dr. Subadra Seshardi	Iron Supplementation to Control Anemia in Pregnant Women: Improving the Coverage, Compliance and Impact through a Decentralized Delivery System and Counseling	1996-1997	India	BP
Dr. Suttalak Smitasiri (ICRW)	Sustaining Behavior Change to Enhance Micronutrient Status through Community and Women-Based Interventions	1996-1999	Thailand	I

Dr. Rebecca Stoltzfus	Development of Simple Breastmilk Indicators to Assess Vitamin A and Iodine Deficiencies in Communities	1995-1998	USA/ Indonesia	M
Dr. G. Subbulakshmi	Pen-Friend Approach in Changing Micronutrient Malnutrition Related Behaviors	1996-1997	India	BP
Dr. E.E.K. Takyi	Bioavailability of Carotenoids from Leafy Vegetables Consumed by Pre-school Children in Northern Ghana	1997-1998	Ghana	I
Dr. David Thurnham Dr. George McCabe	Impact of Infection on Vitamin A Status	1997-2000	UK/USA	M
Dr. Sampson Tsou	Enhancing Iron Bioavailability of Vegetables through Proper Preparation	1995-1998	Taiwan	M
Dr. Stanley Zlotkin	Micro-Encapsulated Iron Supplements: Field Trial Proposal	1997-1999	Canada/ Nicaragua	I
Dr. Stanley Zlotkin	The Bioavailability of a Micro-Encapsulated Iron Supplement using Stable Isotope Methodology	1997-1999	Canada Sri Lanka	M
Dr. Stanley Zlotkin	Micro-Encapsulated Iron and Vitamin A Supplements (Sprinkles) to Treat and Prevent Iron and Vitamin A Deficiency: Field Trial Proposal & Assessment of Dried Filter Paper Plasma Spot Method for Measurement of Soluble Transferring Receptors (STFR) to Assess Iron Status in a Field Study of Iron Deficiency Anemia in Infants in the Kintampo Region of Ghana	1999-2000 Phase 1	Canada/ * Ghana	I

Methodological M

Intervention I

Best Practises BP

* Project will be completed under the Micronutrient Global Leadership Cooperative Agreement (HRN-A-00-98-00027-00)

Table 2: OMNI Research-sponsored Expert Consultations

Micronutrient Interactions: Impact on Child Health and Nutrition

July 29-30, 1996 in Washington, DC

43 participants – 8 from developing countries

Co-sponsored by the Food and Agriculture Organization of the United Nations

Purpose: to the impact of micronutrient interactions on nutrient bioavailability and nutritional status, food processing techniques, that can improve the micronutrient content and bioavailability in complementary foods, and past experience with complementary feeding programs.

Output: ILSI Press document by the same name

Quality Assurance Systems for Improved Nutrition in Developing Countries

May 29-30, 1997 in Washington, DC

38 Participants – 8 from developing countries

Purpose: to document the critical components of a quality assurance system for manufacturing fortified foods in developing countries, including material handling and distribution.

Output: Quality assurance manual in preparation as an ILSI Press document

IVACG Simplified Dietary Assessment Guidelines Workshop

March 12-13, 1998 in Washington, DC

25 participants – 11 from developing countries

Purpose: to revise the IVACG guidelines based on developing country experience in using them.

Output: No-product - consultant hired to revise guidelines based on the workshop discussions did not deliver the product.

Consultative Meeting on Iron and Maternal Mortality in the Developing World

July 6-7, 1998 in Washington, DC

42 participants – 7 from developing countries

Purpose: to examine the evidence supporting a role for iron deficiency anemia in maternal mortality in developing countries.

Output: Supplement to the American Journal of Clinical Nutrition

Micronutrients and Infection

October 4-6, 1998 in Southampton, United Kingdom

39 participants – 8 from developing countries

Cosponsored by the Wellcome Trust

Purpose: to identify important research questions related to micronutrients and infection and to stimulate collaborative research programs among nutritionists, immunologists, bacteriologists and virologists.

Output: Short statement summarizing the state of the science

OMNI Research Evaluation Workshop

March 1-2, 2000 in Washington, DC
20 participants – 3 from developing countries

Purpose: to review the validity and significance of the findings from the OMNI Research grants and the process for selecting and monitoring these grants

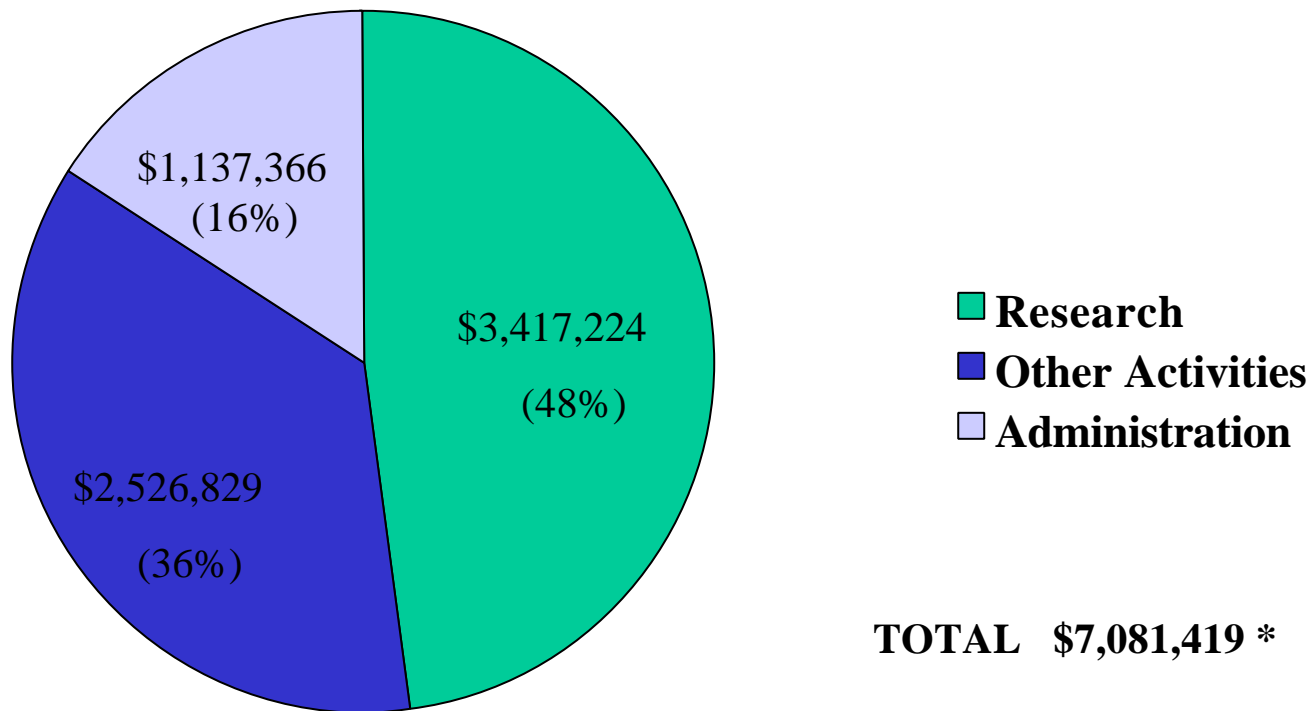
Output: The individual reviews and workshop discussion were used to develop this report.

Table 3: OMNI Research Publications

Author	Title	Date
Workneh Ayalew Zewdie W. Gebriel Habtemariam Kassa	“Reducing Vitamin A Deficiency in Ethiopia: Linkages with a Women-Focused Dairy Goat Farming Project”	ICRW, 1999
Omar Dary Stuart Blumenfeld Agide Gorgatti	“A Guide to the Implantation of a Quality Assurance System for Fortified Foods in Developing Countries”	In preparation
Alizon Draper Penelope Nestel	“Formative Research on Factors Influencing the Acceptability of Different Dispensing Technologies and Formulations of Iron and Multi-micronutrient Supplements”	In preparation
Rosalind Gibson	“A Guide to Using an Interactive 24-hour Recall for Assessing the Adequacy of Iron and Zinc Intakes in Rural Communities”	ILSI Press, 2000
Vital Hagenimana Mary Anyango Oyunga	“The Effect of Women Farmer’s Adoption of Orange-Fleshed Sweet Potatoes: Raising Vitamin A Intake in Kenya”	ICRW, 1999
Charlotte Johnson-Welch	“Focusing on Women Works: Research on Improving Micronutrients Status through Food-Based Interventions”	ICRW, 1999
Kathleen M. Kruz Charlotte Johnson-Welch	“Enhancing Nutrition Results: The Case for a Women’s Resources Approach”	ICRW, 2000
Ritu Nalubola Penelope Nestel	“Inventory of Vitamin A Research & Programs Activities Related to Child Survival in Developing Countries” (2 editions)	ILSI Press, 1999 ILSI Press, 2000
Ritu Nalubola Penelope Nestel	“A Review of the Effect of Vitamin A Nutriture on Health”	ILSI Press, 1999

National Academy of Science	“Prevention of Micronutrient Deficiencies: Tools for Policymakers and Public Health Workers”	National Academy Press, 1997
Delia Rodriguez - Amaya	“A Guide to Carotenoid Analysis in Foods”	ILSI Press, 1999
David Rush	“Nutrition and Maternal Morality in the Developing World”	American Journal of Clinical Nutrition 2000; 71 (supplement)
Nair Carrasco Sanes Rosa Maria Door de Ubillas Irma S. Guillen S.M. Ferreira	“Increasing Women’s Involvement in Community Decision-Making: A Means to Improve Iron Status”	ICRW, 1998
Suttlak Smitasiri Sakorn Dhanamitta	“Sustaining Behavior Change to Enhance Micronutrient Status: Community and Women - Based Interventions in Thailand”	ICRW, 1999
Wellcome Trust/USAID	“The Role of Micronutrients in the Immune Response to Infectious Diseases”	ILSI Press, 1999

Figure 1: OMNI Research FUND SUMMARY



* - does not include indirect costs

Appendix 1: Final Report From The International Center for Research on Women

Appendix 2

OMNI Research Peer Review Panel Members

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Appendix 3: OMNI Research Request for Proposals

Quality Assurance and Control System for Vitamin A, Iron or Iodine Fortified Food

Development and Validation of Simple Methods for Individual Assessment or Rapid Community Screening of Iron, Vitamin A and Iodine Deficiencies

Development of Strategies to Increase and Test Bioavailability of Vitamin A and Iron from Diets

Effective Communications to Resolve Micronutrient Deficiencies

Assessing Costs of Micronutrient Interventions

Development of Improved Delivery Systems for Iron Supplements

Development of Improved Field Methods for Testing Micronutrients in Fortified Foods

Development of Improved Methods for Processing and Packaging Fortified Complimentary Weaning Foods

Resolving Micronutrient Deficiencies: A Women-centered Approach

Appendix 4: Other OMNI Research - Funded Activities

Investigator	Affiliation	OMNI Research Activity	Time Frame
Dr. Paul Arthur	Kintampo Health Research Centre	Funded proposal development meeting – Ghana maternal mortality trial	1998
Dr. Josefina Bonilla	Consultant in Nicaragua – Ministry of Health	Completed OMNI-funded sugar fortification project	1998-1999
Dr. Anna Coutsooudis	The Vitamin A Group – South Africa, University of Natal	Funding to bring South Africans to the XIX IVACG meeting in Durban and to provide administrative support to the local committee. Also supported a breast feeding promotion program in Cato Manor, South Africa to help reduce vitamin A deficiency in infants.	1999-2000
Dr. James Deane	Panos Institute, London, UK	To produce audio features on health, child health and nutrition (particularly vitamin A)	1999-2000
Dr. Olga Garcia	University of California Davis	Developed a short statement on the role of vitamin C enhancement of iron absorption – (decided not to publish)	1999
Dr. Stuart Gillespie	Consultant, UK	Organized workshop “Evaluation of Nutrition Programs” held in conjunction with the 16 th International Congress of Nutrition in Montreal, Canada and drafted workshop report	1997
Mr. Jesse Greene	Consultant, US	Developed advocacy video on vitamin A to use with VITA partners.	1998
Dr. Christopher Howson	National Academies of Science Board of International Health	Developed a report on successful strategies to prevent micronutrient malnutrition using a panel of experts.	1996-1997

Mr. Roger Moffat	Consultant, US	Facilitated commitments between USAID and VITA partners.	1998-1999
Dr. Ritu Nalubola	Consultant, US	For “The Effects of Vitamin A Nutriture on Health: Review of Scientific Studies” and the vitamin A inventory	1998
Dr. Penelope Nestel	Long-Term Consultant/US	<p>Performed number of essential tasks:</p> <ul style="list-style-type: none"> ? Oversaw progress with the “Efficiency Trial for Iron Fortified Wheat Flour” in Sri Lanka ? Worked with Dr. Nalabola on the Vitamin A inventory (2 editions) and the Vitamin A nutriture publication ? Monitored the Draper project ? Monitored the Thurnham project ? Helped Wellcome Trust organize a multi-disciplinary meeting on Micronutrients and Infection held in October 1998 ? Worked with USAID/India to develop and implement a micronutrient plan ? Helped organize the “ Nutrition and Maternal Morality” workshop and edited manuscripts and discussion transcripts for publication ? Prepared a paper on “Effectiveness of Increased Intake of Carotene’s on Vitamin A status” and delivered it at the Latin American Regional Meeting on Cartotenoids in Campinas, Brazil in September, 1998 ? Prepared sections of a manual on wheat fortification with iron (in collaboration with MOST and the Micronutrient Initiative) ? Helped organize and complete the OMNI Research Evaluation Workshop 	1998-2000
Dr. Mary Oyunga	Kenya Agricultural Research Institute	Funded to present ICRW grant results to “Women farmers: enhancing rights and productivity” conference in Bonn, Germany, August 26-27, 1999. Presented “ The Effect of Women Farmer’s adoption of Orange-Fleshed Sweet Potatoes: Raising Vitamin A Intake in Kenya”	1999

Dr. Mary Oyunga	Kenya Agricultural Research Institute	Publications from sweet potatoes project: Nutrition Education for Vitamin A, Ndhiwa, Nyarongi and Rongo Divisions, Homabay District, Nyanza, Province, Kenya. (18 pages – 20 copies); “Orange-fleshed sweet potato varieties for increased vitamin A consumption” (400 copies – 2 pages); and “Sweet potato recipes for increased intake of vitamin A” (400 copies – 2 pages)	1998
Dr. Sonya Rabneck	ACC/SCN	Funded publications: ? Fourth Report on the World Nutrition Situation ? Nutrition Policy Papers on Low Birth weight - Bangladesh ? Nutrition Policy Paper on Countries in Transition ? SCN News #18 and #20 ? Nutrition Policy Paper on Nutrition Stocktaking	1999-2000
Dr. Delia Rodriguez – Amaya	Cidade Universitaria, Sao Paulo, Brazil	For writing “A Practical Guide to Measuring Provitamin A and Major Non-provitamin A Carotenoids in Foods”	1998-1999
Dr. David Rush	Tufts University	Prepared 2 literature reviews: Nutrition and maternal mortality in developing world and Nutrition and pre-natal mortality in the developing world	1998-2000
Dr. Noel Solomons	International Nutrition Foundation, Boston, MA and Guatemala	Provided four papers for publication: 1) Overview paper on performed Vitamin A 2) Sweet Potato Buds I 3) Sweet Potato Buds II 4) Sweet Potato Buds III	1998-2000
Dr. Won Song	Michigan State University	Developed software for analyzing dietary data that will be used in the Sri Lanka iron fortification of wheat flour trial	2000
Prof. Thomas Wikramanayake	Consultant, Sri Lanka	Provided on-site oversight for the “Efficacy trial for iron fortified wheat flour” in Sri Lanka	1998-1999

Appendix 5. Contacts for VITA

BASF Corporation
Best Foods
Cargill, Incorporated
General Mills
H.J. Heinz Company
Kellogg Company
Mars, Incorporated
Monsanto Company
The Proctor & Gamble Company
Roche Vitamins Incorporated
Tate & Lyle Specialty Sweeteners
Unilever

Appendix 6: Results of OMNI Research Grants

Category 1: Dietary Assessment and Improvement, Including Factors That Affect Absorption

? High carotene fruits and vegetables as a potential source of vitamin A in breastmilk of Honduran women

Louise M. Canfield, University of Arizona

Purpose: Using a placebo-controlled, double blind study design, determine whether consumption foods high in provitamin A carotenoids or supplements by the mother will increase beta-carotene concentration in serum and/or breastmilk of the mother and her infant. 150 lactating mothers and their infants were assigned to receive 90 mg beta-carotene over a month period as food or as a supplement, or to the placebo group. The supplement group also received additional dietary fat with the beta-carotene.

Findings: Increases in serum and breastmilk beta-carotene were found in women who consumed foods high in provitamin A carotenoids and those who consumed supplements. These increases did not appear to improve the serum retinol levels of the mothers compared to placebo, however serum values for infants in the two treatment groups were elevated compared to the placebo. Mothers in the placebo group spontaneously increased consumption of beta-carotene rich foods during the study.

Limitations: Baseline dietary data were not analyzed for the women. Lack of food composition tables covering the foods consumed by this population prohibited the analysis of dietary data. Nutritional status data based on child anthropometry were not presented.

? A validation of a simplified dietary method for the assessment of vitamin A deficiency in Niger

Helen Delisle, University of Montreal

Purpose: An observational study to compare the validity of a short food frequency questionnaire against three days of weighed food records and biochemical assessment of vitamin A intake and status (serum retinol and modified relative dose response (MRDR) test) in children aged 2-4 years of age. Two surveys were conducted, 10-12 months apart during the rainy season, the peak period for consumption of green leaves.

Findings: Neither serum carotenoid nor serum retinol levels were significantly correlated with dietary vitamin A intake, although MRDR values were. The short food frequency questionnaire overestimated vitamin A intake compared to weighed food records, especially for animal products. The weekly consumption index appears to be the preferable tool for classifying children into risk categories.

Limitations: Better understanding of the true bioavailability of beta-carotene from food sources such as the green leaves consumed in this study are needed.

? **Dietary fat and infection: relationship to vitamin A status of women and their infants: breastmilk retinol/carotenoids and dietary assessment**

Methodology

George Fuchs and Dewan Alam, International Center for Diarrheal Disease Research, Bangladesh

Purpose: To determine 1) if an intervention to increase dietary fat will result in improved maternal vitamin A status, breastmilk retinol/carotenoid concentration and vitamin A status of breast feeding infants, 2) the relationship between diarrheal/respiratory tract infections and maternal vitamin A status, breastmilk retinol/carotenoid concentration and vitamin A status of breast feeding infants, 3) if the IVACG simplified dietary assessment can be modified to assess risk for vitamin A deficiency in pregnant and lactating women, and 4) if dietary fat and infection effect the IVACG assessment tool and how to improve its accuracy. The study design was a longitudinal controlled intervention trial based on clusters of villages. Treatment was 20 ml soybean oil fed daily during pregnancy and lactation. No placebo was given to the control participants.

Findings: Increased fat consumption improved vitamin A status but did not achieve adequacy. There was no impact on infant vitamin A status measured at 6 months of age. Diarrheal disease appears to negatively impact on plasma retinol levels in pregnant women with low fat intake. The IVACG Simplified Dietary Assessment method is consistent with risk for vitamin A deficiency at the population level but yields significant misclassification when applied to individuals. Dietary fat has no impact on the IVACG method.

Limitations: More in-depth statistical analysis is needed to support the findings. Report was not reviewed during the OMNI Research Evaluation Workshop.

? **Use of biomarkers to validate a dietary tool designed to assess risk of inadequate intakes of iron and zinc in developing countries**
Rosalind Gibson, University of Otago, carried out in Malawi

Purpose: To validate a modified interactive 24-hour recall procedure for assessing iron and zinc status using biochemical indicators of iron and zinc status of women in Malawi.

Findings: Prevalence of inadequate intakes was 39 percent for iron and 36 percent for zinc. Prevalence estimates for iron and zinc inadequacy were similar using biochemical and dietary measures, indicating that dietary data are useful for determining the prevalence of inadequacy.

Infection and gravida were identified as predictors of iron and zinc inadequacy. Iron and zinc availability can be increased by good selection and preparation strategies that lower phytate intake, i.e., using refined or fermented maize flour, and soaking grains to increase phytase activity.

Limitations: Because of the large day to day variation in intakes, it was not possible to demonstrate a direct relationship between dietary intake values and biochemical values at the individual level. Adjusting dietary data for the effect of day-to-day variation before calculating the prevalence of inadequate intakes may overcome this problem. Sensitivity and specificity of the dietary measures would be useful.

- ? **The effects of women farmers' adoption of orange-fleshed sweet potatoes: raising vitamin A intake in Kenya**
V. Hagenimana, International Potato Centre, Kenya, M.A. Oyunga, J. Low, S.M. Njoroge, S.T. Gichuki, J. Kabira

Purpose: To increase dietary intake of vitamin A among at-risk children through the introduction and promotion of orange-fleshed sweet potatoes to women farmers, and processing and preparation of meals using the new varieties.

Findings: There was the significant increase in dietary intake of vitamin A among children whose mothers participated in the agriculture and health/nutrition intervention as compared to children whose mothers received the agriculture-only intervention.

Limitations: The study design is weak. The HKI dietary assessment tool is used as a proxy for consumption of vitamin A-rich foods, but the ability of this tool to detect change in vitamin A status of intake of vitamin A-rich foods is not shown. Duration of the intervention was too short.

- ? **Health and nutrition in Central Asia: analysis of dietary data from the Kyzyl-Orda District of Kazakhstan**
Suraiya Ismail and Hereward Hill, London School of Hygiene and Tropical Medicine

Purpose: To analyze quantitative information on food consumption (24-hour recall data) of 800 women and 400 children from the Kyzyl-Orda region of Kazakhstan. Qualitative information (food frequency questionnaire) for 4000 women and 2000 children were also analyzed. The goal was to provide information on which to develop strategies to improve diet quality.

Findings: Well above two-thirds of the Kazakh women had inadequate intakes of vitamin C and vitamin A, and more than one-third of the women had inadequate intakes of iron and calcium. A large proportion of women had inadequate bioavailable iron intake due primarily to high intake of phytate and tea, plus

inadequate intake of vitamin C. Children's diets were similar to that of the women, inadequate in calcium, iron, vitamin C and vitamin A. Consumption of bioavailable iron was higher than that of women due to lower tea consumption and increased consumption of fruits and vegetables. Home food production is an important determinant of dietary adequacy in this population.

Limitations: The usual constraints of dietary data.

? **Validity of vitamin A dietary intake methodology: effect of dietary fat and infection**

Somluck Nimsakul, Dewan Alam, and George Fuchs, ICDDR, Bangladesh

Purpose: To determine the effect of increasing dietary fat intake (4.5 g soybean oil with each meal for one year compared to 2 ml soy sauce) on vitamin A status in children (under 6 years of age) using the IVACG simplified dietary assessment method and the Helen Keller Institute (HKI) method.

Findings: Both dietary assessment tools found a high risk of vitamin A deficiency at baseline. After the intervention, the HKI method continued to show a high risk while the IVACG method indicated a moderate risk. The usual pattern of food intake was more accurate than the consumption index when compared with biochemical measures of vitamin A deficiency. Increasing fat intake to 20 percent of total calories did not improve vitamin A status as measured by plasma retinol, but did improve vitamin A status when measured with conjunctival impression cytology (CIC).

Limitations: More in-depth statistical treatment is necessary to support conclusions. The amount of oil fed varied during the study. This report was not reviewed during the OMNI Research Evaluation Workshop.

? **Bioavailability of carotenoids from leafy vegetables consumed by pre-school children in northern Ghana**

Etor E.K. Takyi, Noguchi Memorial Research Institute, University of Ghana

Purpose: To explore the possibility of using cassava and kapok to enhance the retinol status of preschool children (2.5-6 years of age; n=519) using a randomized double-blind controlled study with green leaves with and without fat supplemented meals. The trial included a supplementation group (400 retinol equivalents) and a group treated with mebendazole. The meals were fed once a day, seven days a week for 12 weeks. Serum retinol, hemoglobin, markers for acute infection, anthropometric measurements, and worm infestation were measured.

Findings: Daily consumption of pounded, homogenized dark green leafy vegetables supplying 400 retinol equivalents of vitamin A significantly improved

serum retinol levels in these children. The level of fat in the leafy vegetable supplement (10.1 vs 2.6 percent by weight) had little impact on the improvement in serum retinol levels (26.5 vs 23.4 percent). The group that received the leafy vegetable supplement with higher fat plus deworming showed the greatest improvement (38.8 percent). The improvement in serum retinol levels was almost as great in the group that received the leafy vegetable supplement plus deworming (38.8 percent) as in the supplement group without deworming (44.1 percent).

Limitations: More focus on the process of pounding and homogenizing the leaves to increase bioavailability is needed.

- ? **Reducing vitamin A deficiency in Ethiopia: Linkages with a women-focused dairy goat farming project**
W. Ayalew, FARM Africa, Z.W. Gebriel, H. Kassa

Purpose: To improve vitamin A dietary intake among children 1 to 5 years by reducing household-level constraints of women who participated in a dairy goat development project.

Findings: An intervention that included building skills in agriculture production, food preparation and feeding practices, increasing health and nutrition knowledge, and improving access to agricultural inputs is feasible and somewhat effective in improving dietary intake of vitamin A among young children. Factors that reduced risk of vitamin A deficiency included ownership of cattle (an indicator of wealth), milk consumption, food frequency scores and the presence of a home garden.

Limitations: Cross-sectional nature of the data (post-intervention data only) limits the interpretation of results. Self-selection of trial intervention participants makes post-intervention analysis inappropriate. The conclusion that the HKI dietary assessment score is reliable is not supported by the data presented.

Category 2: Iron Laboratory Indicators and Bioavailability

- ? **The evaluation of iron status of children in the presence of infection: effects of iron supplementation on iron status, infection and morbidity**
Namanjeet Ahluwalia, The Pennsylvania State University, carried out in Sri Lanka

Purpose: To determine if higher cut-off values for serum ferritin are needed in populations (children 5-10 years of age) with chronic underlying infections and inflammation. The study will examine the effect of iron supplementation on inflammatory status and morbidity in these children, compared to non-supplemented controls. The study will also evaluate the performance of a filter paper-based ferritin assay compared to the conventional assay.

This study was delayed because of the in-country situation and will be completed under the Micronutrient Global Leadership cooperative agreement.

? **Practical food sources of ascorbic acid to increase dietary iron availability**
Lindsay Allen, University of California, Davis, carried out in Mexico

Purpose: To study the effects of ascorbic acid on iron absorption from single meals, as well as during a two-week period, using stable isotopic iron (^{57}Fe). Changes in iron status were also measured in the non-anemic, iron deficient women (n=21 per group). The vehicle for increasing ascorbic acid intakes was agua de limon.

Findings: Multiple doses of ascorbic (25 mg) increased absorption of stable isotopic iron two fold (13.6 to 23.1 percent). Supplemental ascorbic acid for a two week period using agua de limon sufficient to provide 25 mg of vitamin C twice a day increased iron absorption from 6.6 to 22.9 percent.

However, in an eight month community trial comparing supplemented to unsupplemented women, there was no difference in iron status (rise in serum ferritin or transferring receptor). Thus, other factors beyond dietary iron bioavailability may be limiting ferritin response in this population. A multi-level intervention to increase total iron, decrease inhibitory food components, and improve general micronutrient status (i.e. vitamin A and B-12) may be necessary.

Limitations: The community trial had a small sample size. The amount of vitamin C delivered may have been too small to affect an impact.

? **Increasing women's involvement in community decision making: A means to improve iron status**
N. Carrasco Sanes, CEPREN, Peru, G. Door de Ubillas, I. S. Guillen, and S. M. Ferreria

Purpose: To reduce anemia of women who are members of the community kitchens by improving nutritional quality of meals prepared by the kitchens and increasing consumption of those improved meals.

Findings: Investing in women as critical thinkers, problem solvers and managers led to improve nutritional quality of meals prepared in the kitchens, significant increases in dietary intake of key nutrients such as heme iron and vitamin C, and significant reduction of anemia among members of community kitchens. Improving the quality of service in the community kitchens including physical infrastructure and nutritional content of the meals, and organizational management contributed to explaining the nutritional outcomes. Cost-recovery measures including the use of sliding scales for meal purchase prices and increased demand for the meals sold in the kitchens reduced the average

production costs for the meals, suggesting that the kitchens could, over time, reduce their dependency on external subsidies and become self-sustaining.

Limitations: The sample may not be representative, as they were self-selected. Anemia was not overcome which could be due to the relatively short time frame for the food-based intervention and the lack of a mass media component. There was limited tracking of dropouts.

? **EDTA to reduce anemia**

David Nelson, National Health Research Institute, Ecuador

Purpose: To assess the effect of EDTA on the bioavailability of naturally-occurring food iron. To establish physical and organoleptic conditions for the addition of EDTA to salt for household use and determine the cost effectiveness of this strategy for reducing iron deficiency anemia.

Findings: It is feasible to add EDTA to salt in a peri-urban area in Ecuador. A two-stage, dry-mix method for preparing a homogenous salt-EDTA mixture was developed in which a 1.12 percent EDTA premix was mixed with bulk salt to prepare 100 kg lots.

However, in a community trial with 519 non-pregnant women of childbearing age (15-50 years), 83 children (under 5 years) and 28 children (6-14 years) failed to demonstrate improvement in iron status (hemoglobin, serum ferritin). Hemoglobin values rose in both treatment and controls after six and twelve months of the intervention.

Limitations: There was a substantial drop-out in the community trial (55 percent). Only salt added to foods at home was fortified. How this salt was used (added to cooking water that was discarded) needs to be more accurately determined. Iron content of the normal diet also needs to be determined. There was no positive control, so it is not possible to determine if EDTA fortification may have been more successful than fortification with another compound.

? **Efficacy trial for iron fortified wheat flour**

J.L. Senarantne, Ministry of Plan Implementation and Parliamentary Affairs, Sri Lanka

Purpose: To determine if iron fortified wheat flour is effective in reducing anemia in women and children associated with tea estates. The impact of flour fortified with hydrogen reduced iron (66 mg/kg flour) or electrolytic iron (66 mg/kg flour) on iron status will be compared along with a control (non-fortified flour). Impact on growth of the children, worker productivity and school absenteeism will also be measured. Cost-effectiveness of the fortified flour will be determined as well.

All data have been collected. In-depth analysis of these data will be carried out by Dr. Penelope Nestel, under the Micronutrient Global Leadership cooperative agreement.

? **Enhancing iron bioavailability of vegetables through proper preparation**
Samson Tsou, Asian Vegetable Research and Development Center, Taiwan

Purpose: To determine if various heating methods and other preparation methods improve iron bioavailability from specific vegetables using stable isotope methodology to determine absorption in human subjects.

Findings: Cooking can significantly modify the apparent absorption of iron from a number of vegetables. Tomato is high in bioavailable iron and can promote iron absorption from other sources with less bioavailable iron in humans (measured by excretion of ^{57}Fe from a labeled pancake). Mung bean sprouts are another source of bioavailable iron.

Limitations: No direct connection between *in vitro* apparent bioavailability and true iron absorption.

? **Determining the bioavailability of microencapsulated iron supplement using stable isotope methodology**
Stanley Zlotkin, University of Toronto, carried out in Sri Lanka

Purpose: To determine the bioavailability of microencapsulated ferrous fumarate vs non-coated ferrous fumarate in both rice-based and wheat-based weaning foods using stable isotope methodology. Study subjects were infants (mean age 33.6 months).

Findings: The non-encapsulated form was more bioavailable than the encapsulated form. Both test meals performed equally well.

Limitations: The encapsulation, done in the P.I.'s laboratory resulted in a thicker coating than expected. Testing with a commercially prepared sample is needed.

? **Microencapsulated iron/zinc sprinkles: Nicaragua field trial**
Stanley Zlotkin, University of Toronto, and Margarita Perez, National Autonomous University of Nicaragua

Purpose: To test through a randomized double-blind controlled trial the efficacy to prevent anemia and compliance of microencapsulated ferrous fumarate added as a preweighed sachet to complementary weaning foods. Subjects were Nicaraguan infants between 22 and 26 weeks of age with a hemoglobin of $<100\text{g/L}$. There were four treatment groups – placebo, iron sprinkles (12.5 mg elemental iron as ferrous fumarate), iron/zinc sprinkles (12.5 mg elemental iron as

ferrous fumarate + 5 mg zinc as zinc sulfate, and iron drops (12 mg elemental iron as ferrous sulfate). The treatments were given for six months.

Findings: There was no difference in mean hemoglobin values between the placebo, iron sachet and iron drops groups at the end of the study. All declined. The iron + zinc group was significantly lower than the iron drops group. The groups were not significantly different from one another at baseline. Serum ferritin values declined in all groups. The sprinkles were well-accepted by the mothers

Limitations: In vitro bioavailability testing of the microencapsulated iron sprinkles indicated poor bioavailability. It is unclear why the iron drops group did not improve their hemoglobin status compared to placebo. No infection markers were measured.

- ? **Use of microencapsulated iron and ascorbic acid (sprinkles) and ferrous sulfate drops to treat iron deficiency anemia**
Dr. Stanley Zlotkin, University of Toronto, and Dr. Paul Arthur, Kintampo Health Research Centre, Ghana

Purpose: To determine if ferrous sulfate drops (40 mg elemental iron) given either once a day or divided into three doses (positive control) improved anemia rates in infants, 6-24 months of age with hemoglobin values between 7.0 and 9.9 g/dl. Further to determine if microencapsulated ferrous fumarate (80 mg elemental iron + 50 mg ascorbic acid per sachet) provided as “sprinkles” on a weaning food would also reduce the prevalence of anemia in this population. No placebo group was used. The protocol included biweekly monitoring and educational reinforcement. The study lasted two months.

Findings: All three groups showed a significant increase in hemoglobin over the baseline value. There was no significant difference between treatment groups. Anemia as measured by hemoglobin (HemaCue test) dropped from 100 to forty percent of the study population. Serum ferritin values increased compared to baseline. There were not significant differences between groups. Compliance was very high (80 percent of the children never missed a taking the drops; 68 percent for the sprinkles).

Limitations: Only anemia was measured, not iron deficiency anemia. No measures of infection. Some of the children did not respond to the iron treatment. These children may have been anemic because of other causes.

Category 3: Vitamin A Indicators Including Infection Markers and Their Impact on Vitamin A Measures

- ? **Validation of the ratio of serum retinol-binding protein (RBP) to transthyretin (TTR) as an indicator of vitamin A status**

Francisco Rosales and Catharine Ross, The Pennsylvania State University

Purpose: Using blood samples collected from malaria-infected children in Papua New Guinea, the ratio of RBP:TTR, two negative acute phase proteins, was determined and compared to the children's vitamin A status (serum retinol). Animal data show that RBP:TTR will decline during vitamin A deficiency but not during infection in a vitamin A sufficient animal.

Findings: RBP and TTR are better predictors of serum retinol concentration than any of the other acute phase proteins studied (α 1-acid glycoprotein (AGP), α 1-antichymotrypsin (ACT), C-reactive protein (CRP) and haptoglobin). When both RBP and TTR are reduced, in parallel with a reduction in serum retinol, the reduction is due to inflammation. When TTR is not correlated, a lower serum vitamin A level is likely due to vitamin A deficiency.

Limitations: No samples are "normal" – infection-free children.

? **Continuation of validation of the ratio of serum retinol-binding protein (RBP) to transthyretin (TTR) as an indicator of vitamin A status**
Francisco Rosales, The Pennsylvania State University

Purpose: Using blood from the same study as Ross and Rosales, examined the change in RBP:TTR and serum retinol following vitamin A supplementation compared to controls. The ratio was also compared with liver vitamin A values in 15 surgical patients for measures of sensitivity and specificity, using <0.36 as the cut-off ratio below which one would be vitamin A deficient.

Findings: Based on the liver biopsy specimens, the RBP:TTR ratio with a cut-off at 0.36 provides 71 percent sensitivity and 50 percent specificity. Seven months after receiving a vitamin A supplement or placebo, the number of children with a RBP:TTR < 0.36 declined in the group that received the supplement and not in the placebo group. Both groups had increased numbers of children with a RBP:TTR <0.36 at 13 months post supplementation.

Limitations: Information about the normal distribution of the RBP:TTR ratio is needed. This method should be compared to other methods of vitamin A status assessment.

? **The effect of inflammation on the response of the MRDR and the RBP:TTR ratios to vitamin A supplementation during early infancy**
Francisco Rosales, The Pennsylvania State University

Purpose: To assess the effects of inflammation on the molar ratio of RBP:TTR and the modified dose response (MRDR) test in infants participating in a vitamin A supplementation trial in Ghana. The MRDR were conducted at 6 weeks and 6 months of age, after the infants were assigned to one of four vitamin A

supplementation treatment groups including a placebo. RBP and TTR measures were run at the same time. Acute phase proteins were determined to assess inflammation.

Findings: The determination of serum RBP, TTR and the calculated ratio provided reliable indicators of vitamin A status in 6-week old infants. Serum retinol concentrations were very low, in contrast, with no apparent inflammation. The MRDR measure (3,4 didehydroretinol) was less sensitive to inflammation than serum retinol, RBP or TTR. There is a shift in the distribution of RBP during this phase of life reflecting liver maturation.

The RBP:TTR ratio and the MRDR gave concordant results among 6-month old infants without inflammation, but did not necessarily identify the same individuals. MRDR identified 48 percent of those without inflammation as having vitamin A deficiency; RBP:TTR identified 62 percent. Only 24 infants were identified by both methods.

Limitations: The effect of inflammation on serum 3,4 didehydroretinol concentration compared to serum retinol in children not at risk for vitamin A is needed. Must determine whether the shift in RBP between 6-weeks and 6-months is due to reduced hepatic synthesis of RBP or reduced vitamin A status.

? **Development of simple breastmilk indicators to assess vitamin A and iodine deficiencies in communities**
Rebecca Stoltzfus, Johns Hopkins University, carried out in Indonesia

Purpose: The purpose of this study was to evaluate breastmilk vitamin A and iodine concentration as a community indicator for assessing the risk of maternal vitamin A and iodine deficiencies. Mothers' response to low dose vitamin A supplementation (36 mg vitamin A in the course of 12 capsules given over 4 weeks) and iodized vs non-iodized salt.

Findings: Breastmilk iodine from casual samples is a more efficient indicator of response to iodized salt consumption than was urinary iodine. Milk iodine was more stable than urinary iodine. Neither was a good indicator of risk of elevated infant TSH.

Vitamin A concentrations in full milk samples were equal to serum retinol in determining risk of vitamin A deficiency (as defined by MRDR). However, casual samples were not good indicators. The vitamin A intervention did not elevate milk or serum vitamin A levels except at low vitamin A status.

Limitations: The vitamin A treatment may have been too little to replenish vitamin A stores. More work is needed to determine appropriate cut-offs for breastmilk iodine for different indicator uses.

? **Impact of Infection on Vitamin A Status**

David Thurnham, University of Ulster, Northern Ireland, and George McCabe, Purdue University, Indiana

Purpose: Using cross-project analysis, determine if subclinical infection influences plasma retinol concentrations. Data for acute phase proteins from thirteen data sets, nine of which were from apparently healthy pre-school children, were examined singly, as well as in combination, to determine specific effects as well as 'time-' or 'severity-' based effects on retinol.

Findings: Analysis of the pre-school child data showed that a chronic, subclinical inflammatory state (defined by an elevated α 1-acid glycoprotein (AGP) concentration alone), was associated with a reduction in retinol of 0.1-0.12 μ mole/L whereas the plasma retinol in a child who had a current subclinical infection (defined by elevated AGP and C-reactive protein or AGP and α 1-acid glycoprotein) was depressed by 0.25-0.28 μ mole/L. Inclusion of the data from the other studies, which included children with slide-positive malaria and women who were HIV positive, did not appreciably alter these conclusions.

Limitations: The use of meta-analysis techniques carries limitations based on the variability in the data being combined. These limitations are applicable to this study. This report was not reviewed during the OMNI Research Evaluation Workshop.

Category 4: Behavior Change Including Supplement Distribution

? **Prevention of the negative behavioral effects of iron deficiency in mothers**

John Beard, The Pennsylvania State University and Michael Hendricks, University of Cape Town, South Africa

Purpose: To determine if impaired attention in adolescent mothers, as a result of iron deficiency, has an effect on the mother's interactions with and care-taking ability of her child. Using a double-blind intervention trial (for six months) with iron supplements and a case-controlled non-anemic placebo group, impact on computerized cognitive function tests to determine cognition, emotion, and mother-child interactions will be evaluated and compared to baseline values.

This study is in progress and will be completed under the Micronutrient Global Leadership cooperative agreement.

? **Adaptation and use of quality assurance methods for evaluating a vitamin A communications strategy in Guatemala**

Martha Burdick de Piedrasanta, International Eye Foundation, Guatemala

Purpose: To conduct a feasibility study to determine if private voluntary organizations (PVO) could implement quality assurance (approaches to monitor

and evaluate nutrition communications programs. Pre- and post-test evaluation of vitamin A knowledge was used to determine the impact of the QA approach used in two PVO projects.

Findings: With considerable external assistance, a project that has control over its staff at all levels may be able to institute and benefit from quality assurance procedures.

Limitations: No control group was included, so it is difficult to determine the exact impact of the QA approach. The checklists used as the QA tool do not lend themselves to understanding exactly what the interviewees' misconceptions may be. There is no possibility of detecting a pattern of wrong answers, a systematic pattern pointing to the use of another standard vs a random pattern of wrong answers.

? **Drug dispensing issues for infants and young children: formative research into factors influencing the acceptability of iron and multi-micronutrient supplements and different dispensing technologies**

Alizon Draper, London School of Hygiene and Tropical Medicine, Sam Akor, Hilary Creed-Kanashiro, Lalini Rajakapsa, and Ram Shrestha

Purpose: To determine culturally acceptable forms and packaging for iron supplements aimed at infants and young children. Formative research was carried out in four developing countries to determine knowledge, attitudes and behavior relative to providing micronutrient, specifically iron, supplements of mothers and other care givers.

Findings: A wealth of information was collected about the complexity of health-seeking behaviors. Anemia was not generally seen as priority health issue in relation to young children. Mothers have little concept of prevention; curative interventions for anemia received greater weight. A liquid form (syrup or drops) was preferred. Sprinkles appear to be a viable option also.

Limitations: This qualitative research must be followed-up with quantitative trials using different preparations.

? **Trial of community-based intervention using new behavior change theories to improve the micronutrient status of women and children in Bangladesh**
Claudia Fishman Parvanta, Emory University, carried out in Bangladesh

Purpose: To determine if a communication intervention based on systematic application of behavior change theory will stimulate household actions with the intended goal of increasing women's and children's consumption of vegetables and fruits. A gardening project was the vehicle for behavior change messages. It will be necessary to identify and alter barriers to this behavior change.

Findings: Group interventions were akin to mass media in fostering awareness and limited knowledge change. Strong interpersonal interventions are needed actually change behavior. The investigators identified two promising interventions: 1) individual counseling appropriate for the woman's stage of change and referring to appropriate portions of photonovels; and peer education with no reference to stage, more generic references to photonovels.

Limitations: Inconsistencies of intervention and confounded sampling limit generalizability of results. Although there is a suggestion of greater impact from one-to-one situations, it will be more time-consuming to take this approach.

? **Micronutrient package for tea plantation workers for better health, productivity and profitability**

T. Gopaldas, Tara Consultancy Services, India, and S. Gujral

Purpose: To determine if weekly supplementation with iron (60 mg elemental iron as ferrous sulfate) plus vitamin A (1600 IU) and vitamin D (400 IU), iodized salt (30 ppm used in household cooking) and a nutrition education program (using a simple IEC sheet with dosing regimen and expected benefits) will improve worker health and productivity. Intervention lasted one year. A control plantation was also followed.

Findings: Compared to baseline hemoglobin levels among tea plantation workers increased and clinical signs of vitamin A deficiency decreased in those fed the multiple micronutrient supplements and received nutrition education. These same workers reported fewer "common health problems" compared to baseline and the number of hospital referrals declined. The average amount of tea plucked (in kilograms) increased compared to the control plantation output.

Limitations: The hospital workers were not blinded to the study design and therefore could have influenced the hospital referral pattern. The number of workers declined at the treatment plantation over the course of the project, which maybe the reason that productivity went up. Matched pair analysis would strengthen the analysis.

? **Development of improved delivery system for iron and folate**
Kapil Kaul, Indian Council of Social Marketing

Purpose: To implement a replicable distribution system for iron supplements among adolescent girls through a revised Integrated Child Development Services (ICDS) system. The intervention created demand for the iron/folate supplements and used the ICDS infrastructure, National Service Volunteers, and women's groups to package, distribute and market the supplements. A social marketing campaign based on a comprehensive market review involved folk shows. Deworming was also provided. Change in hemoglobin of the young women was

the measure of success (pre- and post-intervention change and compared to control group).

Findings: The intensive social marketing program using traditional media and a functioning distribution system increased the percentage of adolescent girls who obtained and consumed iron/folate tablets. It is a good example of basing program choices on consumer preferences. The intervention group also had increased hemoglobin values compared to pre-intervention. No change in hemoglobin values was seen in the control group. Using unconventional distributors (Anganwadi workers and student volunteers) was successful.

Limitations: The intervention was intensive making its applicability to other areas outside of India, an issue needing further investigation.

? **A test of social marketing to increase the dietary use of vitamin A-rich leaves by rural people in India**
Balbir Mathur, Trees for Life, Inc., carried out in India

Purpose: To test social marketing techniques to motivate people in rural India to eat drumstick leaves. The one-year campaign in 20 rural villages involved community and family participation. The goal was to create awareness of the benefits of eating drumstick leaves, to motivate community members to plant drumstick trees and to increase the consumption of drumstick leaves.

Findings: Only baseline data were reported along with descriptions of the social marketing techniques. These data reaffirmed that involving communities in “self discovery” is useful and showed a value added effect of involving youth in dramas aimed at increasing knowledge about the leaves.

Limitations: The evaluation phase of the study was not covered under this agreement and so no data are available as to the impact of the social marketing program. There were problems with adequate production of the drumstick trees. Such issues must be addressed prior to undertaking a similar campaign. The campaign is intensive requiring a large investment of time.

? **Iron supplementation through community health workers**
Walter Miranda, National Autonomous University of Nicaragua

Purpose: To test the effectiveness of an iron supplements distribution system based on home visits by community health workers. A culturally appropriate information, education and communication program (home visits with counseling on foods rich in iron and vitamin C) was employed as well. The intervention (distribution of supplements by trained community health workers) was carried out in rural and urban districts. Daily and weekly supplementation regimens were used. Impact was determined by change in iron status (pre- and post-test design

with no control group). All subjects were anemic (<12 g/dl of hemoglobin) at the beginning of the study.

Findings: Women receiving an intervention package consisting of iron folate supplementation, either weekly or daily dosing, with follow-up home visits and counseling showed increased mean hemoglobin levels after three months of intervention. The brigadistas (community health workers) were used successfully to deliver the supplements and to conduct home counseling.

Limitations: The pre- and post- design carries the need for careful environmental control. Factors other than the intervention may have caused the rise in hemoglobin. More investigation of compliance/drop-out rates is necessary. The supplements appeared to be free to the women, so the impact of cost was not explored.

? **Improved solar drying of vitamin A-rich foods by women's groups in the Singida District of Tanzania**

Generose Mulokozi, L. Mselle, C. Mgoba, J.K.L. Mugyabuso, G.D. Ndossi, Tanzanian Food and Nutrition Centre

Purpose: To promote adoption of an improved home-based solar dryer to enhance nutritional quality and year-round availability of vitamin A-rich foods and promote the consumption of these foods by young children.

Findings: Vitamin A dietary intake was significantly greater among children who lived in households that adopted the improved solar dryers than among children whose households did not adopt the dryers. Beta-carotene content of the food products dried in the improved dryers was greater than among those dried using traditional methods.

Limitations: The adopters were self-selected and, therefore, do not represent a random sample. The intervention was short and other nutritional outcomes, beyond vitamin A, were not measured. This study was not reviewed during the OMNI Research Evaluation Workshop.

? **Iron supplementation to control anemia in pregnant women: improving the coverage, compliance and impact through a decentralized delivery system and counseling**

Subadra Seshadri, University of Baroda, India

Purpose: To implement a home-based delivery system for iron/folate supplements to pregnant women with appropriate counseling. Delivery system employed the Anganwadis and Family Welfare Centers in an urban slum area and a management information system. Change in iron status after one year intervention compared to controls was measured.

Findings: Coverage and compliance of the mothers was a function of the amount of time and frequency of visits by health care workers. Hemoglobin levels were not different from baseline at the end of phase 2. The management information system showed promise as a motivator to the health care workers.

Limitations: The control group was not well described and, therefore, it is difficult to draw conclusions about the true impact of the intervention. Appropriate statistical tests were not reported. Cost of the delivery system was not addressed.

? **Sustaining behavior change to enhance micronutrient status: community- and women-based interventions in Thailand**
Suttilak Smitasiri and Sakorn Dhanamitta, Mahidol University, Thailand

Purpose: To improve micronutrient status (iodine, iron and vitamin A) by strengthening women's roles as community leaders and decision-makers. The intervention involved training women leaders in participatory and problem-solving methods, then using these women to support behavior change relative to vitamin A, iron (as supplements) and iodine (as iodized salt) among school girls.

Findings: There were significant improvements in serum retinol, hemoglobin and serum ferritin levels among participant school girls compared to controls (non-participants). Use of iodized salt increased in participant households and mean urinary iodine concentration increased for participant school girls as well.

Limitations: The trial was of short duration. Opportunity costs of the unpaid community women who served as the intervention agents were not known. Overall it is an intensive intervention, which may be difficult to replicate elsewhere in a cost-effective manner.

? **Pen-friend approach in changing micronutrient malnutrition related behaviors**
G. Subbulakshmi, SNT Women's University, India

Purpose: To test the use of children to deliver vitamin A and iron messages to their mothers. The mother's knowledge and an assessment of the quantity and quality of school lunches they packed for their children were measured using a pre- and post- design. 150 separate messages were sent home via the children over a 4-5 month period.

Findings: Sending daily messages home during one school term can improve the nutritional content of lunch boxes (energy content increased, but was still too low). Using the same questionnaire administered twice, mothers' knowledge of nutrition improved.

Limitations: The intervention is applicable only where schools are available and mothers are literate. Cost was not evaluated. Use of the same questionnaire administered twice is of concern.

Category 5: Quality Assurance for Food Fortification

? Evaluation and documentation of quality assurance and control system of fortified foods in Honduras

Maria de Arriola, Central American Research Institute for Industry, Guatemala

Purpose: To assess, strengthen and evaluate an ongoing quality assurance and control (QAC) system for fortified foods, specifically sugar fortification with vitamin A in Honduras.

Findings: Using Quality Control Guides, improvements were documented in the vitamin A concentration in the premix and in the final fortified sugar product, sampled at the plant. Iodine concentrations were found to be stable even before implementation of the Quality Control Guides. Key locations for performing QAC were identified, along with designation of responsible personnel. A detailed manual was prepared.

Limitations: No statistical analyses were reported for the data collected. While the QAC program improved the quality of the fortified sugar at the plant level, leakage of unfortified sugar into warehouses and homes remained a problem.

? Analysis of the strategies used for QAC by the “Operational Fight Against Endemic Goiter and Cretinism in Ecuador” (OFAEGCE) program

Marcos Fornasini, Universidad San Francisco de Quito, Ecuador

Purpose: To identify the cost control steps of the ongoing QAC system, identify critical control points that might adversely affect the QAC system, and provide economical modifications that would improve the effectiveness of the system. The end result would be a methodology to achieve a successful yet economical QAC program.

Findings: The most important features of a successful micronutrient deficiency program are 1) a food fortification program with a QAC system; 2) epidemiological surveillance system; 3) health education; 4) social marketing; and 5) supplements to high risk groups. A successful food fortification system requires a regulatory framework establishing mandatory fortification levels for each vehicle with corresponding enforcement controls. Monitoring must be carried out at the following key sites – manufacturing plants, food outlets, distributors, and consumer sites.

Limitations: The system proposed is complicated and requires a high level of infrastructure within the responsible body, such as the Ministry of Health.

? **A field method for testing iron in fortified foods in Peru**
Dennis Miller, Cornell University, with some work carried out in Peru

Purpose: To develop a simple, affordable, effective and safe portable field kit that can be used as part of a quality assurance program for testing various iron-fortified food products. The method will be validated and the technology used in Peru to evaluate local iron fortified foods.

Findings: Encouraging progress in the development of a simple and easy methodology for iron analysis in foods was made. The testkit is still relatively expensive (US\$2.00 per test). A heating step was incorporated to reduce the time needed to solubilize elemental iron from fortified foods. It works well for wheat flour and crackers, but underestimates iron content in powdered drinks, especially chocolate-flavored drinks with dry milk powder, cereal flours, bean flours and sugar.

Pictorial instructions for how to perform the assay were tested in Peru and found to be user friendly.

Limitations: The time required to solublize the iron is too long limiting the usefulness of the kit in its current form.

Other Projects

? **A randomised double-blind placebo controlled trial to evaluate the impact of vitamin A supplementation on maternal mortality in Ghana**
Paul Arthur, Kintampo Health Research Centre, Ghana

Purpose: This intervention trial will attempt to replicate findings from a similar trial in Nepal. Women, ages 15-45 years, will be given weekly supplementation with 7000µg of vitamin A or a placebo for four years and followed for a range of morbidity endpoints and mortality, both pregnancy-related and non-pregnancy related.

The vast majority of this study will be funded through the Micronutrient Global Leadership cooperative agreement and Department for International Development in the United Kingdom.

Appendix 7: Papers and Presentations Resulting from OMNI Research

PEER-REVIEWED PUBLICATIONS

Gibson RS, Huddle JM, Sub-optimal zinc status in pregnant Malawian women: its association with low intakes of poorly available zinc, frequent reproductive cycling, and malaria. *Am J Clin Nutr* 67:702-9, 1998

Hagenimana V, Carey E, Guchuki ST, Oyunga MA, Imungi JK, Carotenoid contents in fresh, dried and processed sweetpotato products. *Ecology of Food and Nutrition* 37:455-473, 1999

Huddle JM, Gibson RS, Cullinan, TR, Is zinc a limiting nutrient in the diets of rural pregnant Malawian women? *Brit J Nutr* 79:257-265, 1998

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